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09/830,520	07/20/2001	Barbara L. Hempstead	19603/2595	9715

7590

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EXAMINER

NICKOL, GARY B

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 05/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/830,520

Applicant(s)

HEMPSTEAD ET AL.

Examiner

Gary B. Nickol Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 7-16, 18, 19, 26, 27, 29, 30 and 55 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-10, 14-16, 18-19, 26-27, 29-30, and 55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Response to Amendment***

The Amendment filed March 18, 2003 (Paper No. 9) in response to the Office Action of December 20, 2002 is acknowledged and has been entered.

Claims 1-6, 17, 20-25, 28, and 31-54 were cancelled.

Claim 55 was added.

Claims 7-16, 18-19, 26-27, 29-30, and 55 are pending.

Claims 11-13 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

Claims 7-10, 14-16, 18-19, 26-27, 29-30, and 55 are currently under consideration.

**The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.**

**Rejections Maintained:**

Claims 7-10, 14-16, 18-19, 26-27, 29-30 remain rejected and new Claim 55 is rejected under 35 U.S.C. 102(e) as being anticipated by Alps *et al.* (US Patent No. 5,733,871, March 1995) for the reasons of record in Paper No. 8, pages 4-6.

Applicants argue (Paper No. 9, page 5) that the disclosure by Alps *et al.* relates to the treatment of neuronal damage in the central nervous system of individuals in need of such

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treatment wherein the administration of neurotrophic factors like bFGF, aFGF, NGF, BDNF, etc., target neurons to improve survival and limit damage. Applicants further point to the examples in Alps *et al.* which relate to quantifying neuronal damage wherein focal or global ischemia models are used to induce such damage. In contrast, however, Applicants argue that claim 7 (and its dependent claims 8-19, and 55) relates to a method for treating a pathological disorder in a patient comprising administering a trk receptor ligand in an amount effective to treat the pathological disorder by inducing angiogenesis. Applicants further argue that claim 26 (and its dependent claims 27, 29, and 30) relates to a method for treating a pathological disorder in a patient comprising administering a trk receptor ligand in an amount effective to treat the pathological disorder by promoting vessel growth or stabilization. Thus, claims 7 and 26 and their dependent claims relate to the induction of angiogenesis or vessel growth or stabilization to treat a pathological disorder while Alps *et al.* relate to the treatment of neuronal damage which may be caused by disorders such as ischemia, hypoxia, or neurodegeneration due to stroke or cardiac arrest.

These arguments have been carefully considered but are not found persuasive. Independent claims 7 and 26 are broadly drawn to the treatment of *any* pathological disorder in a patient. This includes the treatment of neuronal damage in a patient due to ischemia or hypoxic damage. Also, intravenous administration of trk receptor ligands does not limit the pharmacological activity to one particular cell type (such as neurons) because such administration is systemic. The compounds would interact with any and all cell types that expressed the trk receptor. Moreover, as set for in the previous Action, the disclosure by Alps *et al.* clearly teaches the intravenous administration of the same compounds (trk receptor ligands)

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to the same population of patients such as non-cardiac vascular disorders (i.e. strokes) or vascular disorders (cardiac arrest). Thus, the patent teaches the administration of the claimed compounds to the same population of patients as claimed, with the same route of delivery as claimed and inherently such compounds would effectively induce angiogenesis or promote vessel growth or vessel stabilization.

Furthermore, applicant's arguments directed at the administration of bFGF (Paper No. 9, page 6) wherein an article by Kaplan *et al.* teaches that bFGF is not a trk receptor ligand are not found persuasive because the disclosure by Alps *et al.* is not solely limited to the administration of bFGF. As set for in the previous Action, Alps *et al.* teach that such pathological disorders can be treated following intravenous administration of certain neurotrophins including BDNF, NT3 or NT4 (abstract, column 1, column 5). Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

**All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.**

No claim is allowed.

#### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol Ph.D.  
Examiner  
Art Unit 1642

GBN  
May 16, 2003

  
ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
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